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| 09/582,809 | 06/30/2000 | GEORGE E. SEIDEL | XY-LODO-USNP | 3161 |

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| EXAMINER |
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SZMAL, BRIAN SCOTT

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| ART UNIT | PAPER NUMBER |
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3736

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/582,809

Applicant(s)

SEIDEL ET AL.

Examiner

Brian Szmaj

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-12,16-29 and 165-173 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-9,16-18,23-26,28,166-168,172 and 173 is/are rejected.
- 7) ☒ Claim(s) 10-12,19-22,27,29,165 and 169-171 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Claim Objections

1. Claims 19-22 and 169-173 are objected to because of the following informalities: Claims 19, 169, 170 and 171 refer to cancelled claims 3, 4 and 14. Appropriate correction is required. The above claims will not be acted upon with regards to prior art rejections, until the dependency issues are corrected.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 26, 27, 168, 172 and 173 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 26 and 27 refer to Claim 25, however Claim 25 does not provide sufficient antecedent basis for either Claim 26 or Claim 27. It appears the claims should refer to Claim 24 instead.

Claim 168 claims dependency on Claim 185, of which does not exist in the current application. The Examiner assumes the claim refers to Claim 167 instead.

Claims 172 and 173 claim dependency on Claims 189 and 190, of which do not exist in the current application. The Examiner assumes the dependency of the claims refer to Claims 171 and 172.

Claim Rejections - 35 USC § 103

Art Unit: 3736

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 2, 5-9, 16, 18 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seidel et al ("Insemination of Holstein heifers with very low numbers of unfrozen spermatozoa", 1995) in view of Spaulding ('990).

Seidel et al disclose a means for inseminating heifers with low numbers of sperm cells and further disclose collecting sperm; separating sperm based on the sex characteristic; establishing an insemination sample having a low number of separated sperm cells capable of fertilizing at least one egg within the female of the species at levels comparable to a typical insemination dosage; inserting a portion of the insemination sample into a female; fertilizing at least one egg within the female; producing an offspring mammal; the insemination sample having a success rate selected from the group consisting of at least 35%, at least 41%, at least 50% and at least 90%; inserting the insemination sample both ipsi- and contra-lateral within the uterine horns of the female; inserting the insemination sample deep within the uterine horn; inserting insemination sample into the uterine horn using embryo transfer equipment; and collecting sperm cells from bovine. See Abstract.

Seidel et al however fail to disclose the use of establishing a sperm cell source that supplies sperm cells to be separated; sensing a sex characteristic of the sperm cells; a flow cytometer; establishing a sheath fluid for sperm cells; collecting the sperm cells

having the desired sex characteristic; and providing a high speed sorting flow cytometer, wherein the sperm cells are sorted at a rate of greater than 500 sorts/second.

Spaulding discloses a sex-associated membrane process and method for increasing the probability that offspring will have a desired sex and further disclose establishing a sperm cell source that supplies sperm cells to be separated; sensing a sex characteristic of the sperm cells; a flow cytometer; establishing a sheath fluid for sperm cells; collecting the sperm cells having the desired sex characteristic; and providing a high speed sorting flow cytometer, wherein the sperm cells are sorted at a rate of greater than 500 sorts/second. See Column 7, lines 58-68; and Column 8, lines 1-33.

Since both Seidel et al and Spaulding disclose means for inseminating female mammals, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Seidel et al to include establishing a sperm cell source and sensing the sex characteristic of the sperm cells, as per the teachings of Spaulding, since it would provide a means of generating a sex specific offspring while utilizing a small insemination sample, thereby reducing waste and increasing profits.

6. Claims 17 and 28 and 167 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seidel et al ("Insemination of Holstein heifers with very low numbers of unfrozen spermatozoa", 1995) and Spaulding as applied to claim 16 above, and further in view of Sasaki et al.

Seidel et al and Spaulding, as discussed above, disclose a sex-associated membrane process and method for increasing the probability that offspring will have a desired sex

but fail to disclose cushioning the sperm cells from impact with the collector; avoiding impact with the collector; and operating the flow cytometer in the range of about 5kHz to about 50 kHz.

Sasaki et al disclose a high speed flow cytometric separation method and further disclose cushioning the sperm cells from impact with the collector; avoiding impact with the collector; and operating the flow cytometer in the range of about 5kHz to about 50 kHz. See Column 4, lines 6-16 and 66-67; and Column 5, line 1.

Since Seidel et al, Spaulding and Sasaki et al disclose means for using a flow cytometer, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Seidel et al and Spaulding to include the use of cushioning the cells and operating the flow cytometer in a certain range, as per the teachings of Sasaki et al, since it would provide a means for preventing damage to the cells while providing a high sorting rate.

7. Claims 23, 24, 26 and 166 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seidel et al ("Insemination of Holstein heifers with very low numbers of unfrozen spermatozoa", 1995) and Spaulding as applied to claim 16 above, and further in view of Adair.

Seidel et al and Spaulding, as discussed above, disclose a sex-associated membrane process and method for increasing the probability that offspring will have a desired sex but fail to disclose staining the sperm cells; chemically coordinating a sheath fluid with the pre- and post-sort fluid environments; establishing a sheath fluid that comprises a sodium citrate; and the sodium citrate sheath fluid further comprises egg yolk.

Art Unit: 3736

Adair discloses a method of treating collected mammalian semen and separating the sperm, and further disclose staining the sperm cells; chemically coordinating a sheath fluid with the pre- and post-sort fluid environments; establishing a sheath fluid that comprises a sodium citrate; and the sodium citrate sheath fluid further comprises egg yolk. See Column 3, lines 14-15 and 25-39; and Column 4, lines 6-54.

Since Seidel et al, Spaulding and Adair disclose means for collecting and separating sperm, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Seidel et al and Spaulding to include staining the sperm cells and providing a sheath fluid, as per the teachings of Adair, since it would provide a means of sustaining the sperm cells during and after the separation process, and keep them viable for implantation into a female for artificial insemination. The claimed concentration of stain, as well as the percentage of components in the sheath fluid can be obtained by routine experimentation from the disclosure of Adair.

Allowable Subject Matter

8. Claims 10-12, 27, 29 and 165 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

9. Applicant's arguments, see Paper No. 15, filed May 6, 2003, with respect to the rejection(s) of claim(s) 1, 2, 5-12, 19, 25 and 169-171 under Seidel et al ("Insemination of Holstein heifers with very low numbers of unfrozen spermatozoa", 1995) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Seidel et al ("Insemination of Holstein heifers with very low numbers of unfrozen spermatozoa", 1995), Spaulding ('990), Sasaki et al, and Adair ('246).
10. Applicant's arguments filed May 6, 2003 have been fully considered but they are not persuasive. With regards to the reference of Adair teaching a dilution solution for sperm cells, Adair does in fact teach a dilution solution utilizing egg yolk, glycerol, glucose and citrate (See Column 3, lines 14-15). Nowhere does Adair suggest utilizing pure egg yolk without using glycerol, glucose and citrate, for the dilution solution, as suggested in the remarks on Page 12. The broad disclosure of citrate still encompasses sodium citrate, as claimed by the applicants.
- With regards to Spaulding, the reference discloses a sort rate greater than 500 sorts/second. See Column 8, lines 12-13. The argument that the actual sort rate in the reference of Spaulding was well below 500 sorts/second is respectfully traversed. The sort rate cited in the Remarks (at Column 10, lines 11-13) is for an enriched sample to be sorted and not a standard sample. The flow cytometer that was used was explicitly disclosed as having a sort rate far greater than 500 sorts/second.

Conclusion


Art Unit: 3736

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The citation of Donaldson is disclosed due to the disclosure of producing superovulation in cattle utilizing luteinizing hormones and follicle stimulating hormones, per the requirements of Claims 20 and 21. The reference could not be used in a rejection due to the dependency issued stated above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (703) 308-3737 and group fax number is (703) 308-0758. The examiner can normally be reached on Monday-Friday, with second Fridays off.



BS
September 25, 2003



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